

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 56, 57 and 62-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyd et al. (U.S. Patent 5,558,644).

Regarding claims 1, 56, 57 and 62-65, Boyd et al. teach a catheter for cardiac procedures with a grasping element (Fig. 5, # 71) for holding tissue to be cut (Col. 13, lines 60-61) and cutting blades (Fig. 5, #s 68 & 69) arranged in a pincer configuration. As the blades are on an independent element, they are rotatable relative to the catheter. Both the cutting elements and the grasping element extend from an opening of the catheter and are capable of grasping and severing a chord. The catheter includes an inflatable balloon (Fig. 5, # 11) for stabilizing the catheter within the heart. Since the grasping element is capable of grasping the chord it can constrain the movement of the chord.

Regarding claims 68 and 69, Boyd et al. is capable of performing the claimed function.

A recitation of intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the

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prior art. If so, the recitation serves to limit the claim. However, if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, *i.e.*, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al. (U.S. Patent 5,558,644).

Regarding claims 2 and 66, Boyd et al. do not specifically disclosed the size of the cutting blades, however, a skilled artisan would select the blade configuration best suited for the intended task making the blade size an obvious design consideration. The use of shaped memory elements in catheters is pervasive in the art. One of skill in the art would select such elements to achieve a required shape of an element when deployed from a restricted area such as a catheter lumen.

Claims 58-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al. (U.S. Patent 5,558,644) in view of St. Goar et al. (U.S. Patent 6,629,534).

Regarding claims 58-61, Boyd et al. are discussed above, but do not teach a wire grasping element. St. Goar et al. disclose a cardiac catheter with multiple capture coils (Fig. 32A, # 60 & 62) intended for grasping chordae, the coils may be loops of nitinol (Col. 25, lines

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45-55). The loops being circular, they have portions that are at an acute angle to the opening of the catheter. It would have been obvious to one skilled in the art to use the loops as taught by St. Goar et al. in the invention of Boyd to capture tissue, such as chordae, during a cardiac procedure as both catheters are intended for such procedures and a skilled artisan would be motivated to seek prior work.

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al. (U.S. Patent 5,558,644) in view of Sterman et al. (U.S. Patent 6,283,127).

Regarding claim 67, Boyd et al. are discussed above, but do not teach multiple catheters for a cardiac procedure. The use of multiple access devices for a cardiac procedure is well known as evidenced by Sterman et al. It would have been obvious to one skilled in the art to use multiple access devices as taught by Sterman et al. in the invention of Boyd et al. to allow for different tools with independent positioning.

Response to Arguments

Applicant's amendment to claim 60, necessitates the removal of the previously 112 rejection.

Applicant's arguments filed 6/30/2009 with respect to the rejection of claims 1, 2, 56-67 have been fully considered but they are not persuasive.

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Applicant provides a description/summarization of the criteria that must be met in order to provide a 102 anticipation rejection and a 103 obviousness rejection, see page 6 through 9, 2nd full paragraph. The examiner thanks Applicant for the summarization, but obviously has determined again that the prior art meets these criteria.

On page 9, last paragraph, Applicant asserts:

However, the catheter described in Boyd does not disclose, teach or suggest a catheter comprising an opening in which the grasping arrangement constrains the movement of the chord and through which the cutting arrangement can be provided to sever the at least one chord, as recited in amended independent claim 1. Boyd, on the other hand, describes a catheter through which forceps 71 and blades 68, 69 are provided. The grasping and the cutting are performed outside any opening of the catheter. St. Goar and Sterman do not cure these deficiencies of Boyd, and the Examiner does not allege that they do.

First, it should be clear there is no explicit recitation in claim 1 that precludes the cutting or severing of the chord outside of the opening. It is only claimed that the opening through which the cutting arrangement is provided to sever the at least one chord. Secondly, this recitation, is one of a functional limitation and it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, *i.e.*, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto,

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312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971). Thirdly, the invention of Boyd et al. is clearly capable of performing the recited function limitation.

Next, on page 10, 2nd full paragraph, Applicant asserts none of the prior art discloses that “the distal end of the wire comprises a hook-shaped portion.” It should be noted, that during examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969). Applicant should appreciate that a wire can be broadly interpreted as a thin strip, it is not even necessary that the thin strip be metallic. Clearly, all of the graspers disclosed can be and have been interpreted as a thin strip.

Next, regarding Applicant’s arguments/remarks attacking the rejection of claim 62, any pointed rotatively coupled grasping elements broadly meet the claim. Applicant’s comments with respect to “coupled” or off point as “coupled” is broadly interpreted as directly or indirectly connected by structure or function. Clearly, Applicant must appreciate and admit that the pincers

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97 and 98 of Boyd et al. which are delivered through the lumen of the catheter are therefore coupled to the catheter, see figure 11.

Regarding Applicant's arguments/remarks attacking the rejection of claim 64, it should be noted that the expandible balloon 11 of Boyd et al. extend along and from the catheter, see figure 11. Additionally, the expandible balloon of Boyd et al. is capable of extending to an apex of the ventricle, again see figure 11.

The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.

The rejections have been maintained and this action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit
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